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**DEVELOPMENT OF THE NATIONAL BIOSAFETY FRAMEWORK FOR
THE REPUBLIC OF PANAMA**

FINAL REPORT

2007

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(*) Full legal texts are not included in this report. For original texts, please refer to Spanish version.

I. EXECUTIVE SUMMARY

The national project for the Development of a Biosafety Framework for Biotechnologies for the Republic of Panama was executed by the National Authority of Environment (ANA) thanks to a grant and financial support from the Global Environment Facility. It was conceived to be implemented starting on July 2005 for a period of 27 months, ending on October 2007. The administrative support was provided by the United Nations Development Program (PS00045873).

The Cartagena Protocol on Biosafety (CPB) and Law No. 48 of August 8, 2002 by which the National Commission on Biosafety was established were the basic instruments of reference to determine procedures and limitations to adequate effectively national regulations to the CPB. Panama's main goal was to put into force the necessary adjustments to articulate the recent changes in its government administration so as to count with effective due processes in the administrative and judiciary sectors.

During the initial strategy of the project, a series of meetings and workshops were held with local scientists and professors known for their work in related areas. Most activities were aimed at implementing a plan to promote participation by stakeholders in biosafety decision-making. The National Commission on Biosafety (NC) called for a consultative process to collect information and data on the current status of biosafety and biotechnologies in Panama including human and institutional resources with a profound analysis of the information collected from all stakeholders.

Several surveys with the support of local consultants were carried out in terms of local policies relevant to biosafety including, national development, environment, agriculture and livestock, food security, health and population decrees. Existing legislations of relevance to biosafety and biotechnology categorized into legislations were reviewed as well as programs for risk assessment and management, including assessments of the National Agricultural Research Institutions were survey on public perception of LMO were taken.

The main objective was to establish parameters that could guide the evaluation of existing laws related to biosafety and to look for flaws in the juridical system as well as to identify ways and means to modernize and up-date norms to be able to count upon a system of authorizations and controls by setting rules and procedures for the safe handling, transfer, and use of living modified organisms.

The first step taken was to draw a set of regulations on Law No. 72 through which the CPB was ratified; aware that through these steps certain assurances could be taken to meet a minimum of the Protocol commitments and responsibilities.

However, the constraints that the lack of institutional capacities and expertise created, highlighted even more the complexity of the problem; forcing the members of the NC, to adopt a different strategy and concentrate its efforts upon the regulations of Law No. 48 by which the establishment of the NC was proposed. Without hesitance's it was agreed that an effective regulatory framework on this matter would required of strong institutions that were able to expand the debate

into a multi-sectorial approach to make it operative. Much hope was placed on the regulation of both laws, hoping that this process could define plans and programs of actions according to the urgency notably recognized given the geographical position and increased movement of goods through the Panama Canal.

Two workshops were held with stakeholders and the conclusions and recommendations made it obvious that the strategies and orientations of the project were working against the real objectives that were defined. The results of exchanges, meetings and seminars held among the members of the NC pointed more toward amending the existing law No. 48, so as to be better equipped to adequate Panama's needs in response to the objectives of the CPB.

The main problem with this law had been that in spite of its recent history, it had become obsolete due to structural changes that had taken place during the past two governments. New instances of responsibilities had been created and other schemes of development were being drawn particularly in relation to the expansion and globalizations of world trade that without doubt would influence the regulations and procedures that Panama adopts in matters of transfers, use and liberalization of LMO.

With this in mind, law No. 48 was examined and reviewed trying to find consensus among the entities in terms of sectorial policies so as to count upon an efficient coordination of competences. It became important to have clear and well defined tasks in part due to the increment in cargo and movements of containers in the Colon Free Zone that at the same time has developed new security systems upon which the regulations for LMO had to be incorporated.

One aspect to underline was the prevailing concern in terms of facilitating the users of LMO, be academia or private sector, a framework that would avoid as possible irrelevant steps within the national bureaucracies.

The need to adequate Panama's regulation to the procedures of notifications and control under the Biosafety Clearing-House (BCH) mechanism as well as the national participation in the BCH was pinpointed as a way to enhance research and take advantage of the experience with these schemes in neighboring countries. The increased number of transboundary movements through the isthmus requires of very operational and transparent systems to create trust on the user but also to protect Panamanian from unnecessary risks. Therefore, much effort is being placed in developing the site for Panama's BCH so as to have it in force once the new law is adopted.

The amendments introduced to Law No 48 have been the results of an extensive consultative process, extremely long and complex discussions during the last three years with the participation of all sectors from the civil society and governmental institutions as well. Notwithstanding the interest shown by all participants in defining clear and straight forward procedures. An approach that could allow for public access to information is still pending; in spite of the interest to put it in effect within the next 12 months.

In other words, in the formulation of the regulatory framework a balance has been

seek between guarding safe movements of LMO and the promotion of research and development of new biotechnologies. It has been considered that in the promotion of programs of public awareness, all institutions, be it public or private, must be clearly involved with an in-depth understanding of what this is all about. The capacity building program geared at strengthening human resources which needs to be put into force soon after the amendments to the law are agreed, is still been reviewed so as to start its implementation within the next two years. Finally, the amendments and modifications introduced point to the "establishment and coordination of State policies related to biosafety, handling and of LMO's, products and sub-products to prevent risks and minimized impacts on the environment, biological diversity, human health and agricultural production that could result out of activities related to the use of modern biotechnologies".

The overall results of the past 27 months were satisfactorily accomplished. The lack of expertise without any doubt became an important constraint to the project. The high costs of biotechnological research added a different perspective to the establishment of an effective regulatory system. Many valuable proposals to support national entities to develop technical skills at research and risks evaluation for non-technical institutions as Customs Authority or the National Maritime Authority are still pending due to the lack of financial resources. For the near future, the strengthening of programs gear at capacity building for the scientific community, educators and national authorities is being drawn, through high-level technical training courses that could set a minimum expertise in each of the sectors responsible for the application of the regulatory framework. Several recommendations are presented at the end of the final report reflecting in part the feeling from all the members as to future actions that could build up Panama's commitments to the Cartagena Protocol and national regulations.

II. BACKGROUND

In January 2000, the signatory states of the Convention on Biological Diversity reached an agreement to adopt a Protocol on the Safety of Biotechnology, the object of which is to "contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."

In November of the same year, the Global environment facility, in its 16th term of sessions, approved the "Initial Strategy for assisting countries to prepare for the Protocol's entry into force" (GEF/C.16/4), whose objectives were:

- a) To help countries in the application of the Cartagena Protocol on Biosafety through the development and implementation of national frameworks for biotechnological safety;
- b) To promote the exchange of information and cooperation, especially at a regional and sub-regional level;
- c) To facilitate the cooperation with other organizations to assist in capacity building for the application of the Cartagena Protocol on the Safety of Biotechnology.

At the same meeting, the GEF council also approved the UNEP/GEF Global Project titled "Development of National Biosafety Frameworks" which aims at helping up to 100 eligible countries to prepare their national biosafety frameworks and to facilitate co-operation and the exchange of experiences at a regional and sub-regional level on questions of biosafety frameworks. It is precisely on the basis of this recommendation that the Republic of Panama felt called upon to formulate a regulatory national framework ensuring that the use, release and, in general, the transboundary movement of genetically modified living organisms takes place under regulations which ensure the protection of the health of humans and animals as well as the environment.

At the national level, in early 2001 and on instructions of the Executive Body, the establishment of the National Committee on Biosafety and Bioethics was approved by Executive Decree No. 137 of May 24, 2001 with the aim of publishing the various aspects of importance to Panama's natural environment, and to promote public activities seeking to ascertain the approval of the following bills of law:

1. "Law for the establishment of national regulations regarding the development of activities in the field of genetic engineering and the application of corresponding biosafety measures"
2. "Law for the establishment of a National Codex on Biosafety and Bioethics"

In the same year, Panama ratified the Cartagena Protocol on Biosafety of the Convention on Biological Diversity, passing law No. 72, on December 26th, 2001, published in the Official Gazette No. 24,460 on December 28th, 2001, for which reason the above mentioned drafts were recommitted.

The following year, ANAM, through the National Environmental Program, conducted the study "Standards for the Research, Registration, Trade and Information regarding the Biosafety of Living Organisms, Genetically Modified by new Biotechnologies", a consultancy which helped to prepare a draft for the bill presented before the Panamanian Parliament. Law No. 48 was passed on August 8th, 2002, establishing the National Committee on the Biosafety Genetically Modified Organisms and enacting other provisions, published in the Official Gazette No. 24,617, on August 14th, 2002.

Subsequently, in the year 2003, ANAM obtained the approval of funds from the GEF, through the United Nations Environment Programme, to execute Project N° GF/2716-01-4319, titled "Development of the National Biosafety Framework, Sub-Project for Panama GF/2716-02-4".

The project was intended for a period of 23 months under the responsibility of ANAM as the National Executing Agency (NEA). The basis of the Project is the Sub-Program for Biosafety and Control of Modified Living Organisms of the National Action Plan for Biological Diversity (PANDB) in Panama. of the year 2000, the aim of which in 2005 was the implementation of the legal framework and policies regarding biosafety, in connection with the introduction of species and the control of living modified organisms.

In order to meet the goal of the Sub-Program of Biosafety and Control of Living Modified Organisms, the following short-term steps were agreed upon:

1. Establishment of a unit responsible for all biosafety-related activities.
2. Establishment of biosafety norms in agriculture, regulating the activities of introduction, research, handling, production, transportation, storage, conservation, use and release of living modified organisms, their derivatives and organisms containing them.
3. Design and application of a national policy framework among involved institutions regarding matters of biosafety.
4. Creation and strengthening of the networks or working groups dealing with biosafety in agriculture.

These activities were determined to be implemented in close co-operation with the Ministry of Agricultural Development, the National Management of Aquaculture, presently attached to ARAP, the Institute for Agricultural Research, Universities, National Environmental Authority, the National Network for Biosafety, the National Committee for Biosafety and the civil society; establishing the implementation of the Panamanian regulatory framework for biosafety within the political guidelines for the 2004-2009 five year period.

The main challenge for the national government as well as the scientific community has been the lack of professional as well as institutional expertise; the failure to define the potential of the new biotechnologies in a country that has made neither sufficient efforts nor funds available for the development of science, and even less for the innovation of biotechnology, and finally the absence of the regulatory framework on the biosafety of LGMOs (genetically modified living organisms).

The execution of the project has been aimed at the adoption of procedures, follow-up and controls for the development of new biotechnologies and for the protection from their potential side effects for biodiversity, health and the environment in general. These considerations require the adoption of standards with easy application and the avoidance of overly bureaucratic structures liable to hamper their implementation.

During the last decade, plans and programs for development have been adopted, which brought with them new economic parameters and models, partly through commercial agreements, whose objectives correspond to international commercial interests rather than to priorities for the development of a country, which implies serious consequences for poverty and unemployment.

At the same time, the criteria which have been judged as useful have to meet these challenges, just as the transformation of new centers for development and the urbanization of a large part of the national territory, which entails a demand for new products, whose inputs have to be screened and analyzed with certified scientific methods. This means that the choice of criteria is made difficult, not only due to the lack of information, the complexity and the risks of the new discoveries and their applications, but also the high costs resulting from patents and other such tools, which makes it difficult to obtain full information on the manufacture of products on the basis of genetically modified living organisms.

There are, for example, a series of obligations resulting from the International Plant Protection Convention, obliging Panama to apply the SPS Norm No.11, which deals with risk analysis of quarantine pests and contains, in the annex or supplement to this norm, specific instructions by FAO regarding the risk analysis for pests and genetically modified living organisms. This means the commitments have to be fulfilled, regardless of whether the guidelines make them viable or provide any short term benefits for the country.

There has been some progress in the development of new projects and research like the Biotechnological Programs of the University of Santa Maria La Antigua, several special courses, and a Masters' degree in biotechnology, in the area of agriculture, industry and human health. The Universidad de Panama started in 2005 to offer the first Ph.D.courses in biotechnology. The University of San Martín offers a bachelor and a post-graduate course in biotechnology.

Institute of Advanced Scientific. Investigations and High. Technology Services (INDICASAT) is developing some research projects in modern biotechnology, as it already disposes of highly sophisticated equipment as well as suitable laboratories

and work areas, obtained with the support of the national government and international corporations. An investment of US\$ 2.5 million has been made in equipment and the laboratory and support has been obtained for joint activities with other institutions, among which:

- Center for Biotechnology and Applied Biology,
- Laboratory for Applied Biotechnology of the IDIAP,
- Production Center for Agroindustrial Research of the technological University of Panama
- Research Center for the Detection of Parasite Diseases of the University of Panama
- Laboratory for Environmental Microbiology of the University of Panama
- Gorgas Commemorative Center for Health Studies
- Laboratory for Plant Health of the MIDA
- Special Institute for Analysis (IEA) of the University of Panama
- Laboratory of the Tropical Institute of Medicine and Health Sciences of the Florida State University in Panama
- Smithsonian Tropical Research Institute

The overall objective of the UNEP/GEF Global Project also has made it possible to organize activities leading to:

1. the evaluation of the present technological capacities related to biotechnological safety and the implementation of a National Biosafety Framework;
2. the formulation of proposals to strengthen the national capacities to define valid scientific criteria for biosafety;
3. the strengthening of the national capacities to competently reach decisions regarding notifications and applications related to genetically modified living organisms, including the establishment of administrative systems;
4. the implementation of other measures in accordance with the Cartagena Protocol on Biosafety (CPB);
5. reviewing of the regional and subregional experiences with a view to improving alignment in the application of national procedures;
6. the assignation of tasks in order to ensure public awareness and improve the system for information of the community on questions related to the release of genetically modified living organisms;

Some shortcomings of a practical nature surfaced as a result of the assessments carried out in the framework of the project, among them:

1. There is no documentation on the commercialization and flow within specific sectors in the context of the use of genetically modified living organisms.
2. There are no mechanisms to control the flow of genetically modified living organisms, their derivatives and products which contain them, which are imported or intended for importation.
3. Absence of a system of information detailing the need for national capacities for biosafety and the safe use of genetically modified living organisms.
4. There is no information on the channels of movement of genetically modified living organisms down to the end-consumer, including

administrative and procedural aspects of the movement of these products within the national territory.

5. There is no information on potential risks of contamination to the environment and the biodiversity of the country through the use and handling of genetically modified living organisms.

6. No characterization has been made of public or private actors who participate or should participate in the process of moving genetically modified living organisms, their derivatives or products containing them, from the site of production or importation to that of their commercialization and final consumption.

7. There are serious deficiencies in the technical guidelines regulating the current import procedures regarding genetically modified living organisms (grains, seeds or other reproductive material), which may affect risk assessment and management for their transport, handling and utilization, with the exporting countries, under the terms of the CPB.

8. No limiting factors could be identified in the distribution system of genetically modified living organisms, their derivatives or products containing these, for their safe movement in Panama.

9. There is no experience regarding development and management of risks resulting from the use of genetically modified living organisms in this country.

10. The public is in general unaware of the topic of biosafety and genetically modified living organisms.

This means that, although Panama is on the way to implement regulations which rule all obligations and responsibilities, in order to face an important socio-economic and commercial development under way for five years, it is urgently necessary to establish guidelines which reinforce co-ordination and support between all responsible institutions in this field.

III. OUTLINES OF A NATIONAL BIOSAFETY POLICY

The outlines of policies on biosafety are part of the objectives of the "Outlines of the Policies of the National Environmental Authority for 2004-2009" whose conservation strategies for a sustainable development include:

1. To strengthen ANAM's capacities to exercise its functions as a governing body, for the regulation and control of environmental matters, in order to contribute to the successful transition of the Panamanian society towards sustainable forms of organization.
2. To work in close collaboration with the other state agencies, with the local governments, with the private sector, with the academic community and with the civil society to promote the necessary initiatives to further the competitive advantages of Panama in environmental matters
3. To prioritize the attention on the components of the conservation strategy, appreciation of the country's natural resources and the creation of employment.

It is above all in the latter point where the support for the scientific programs associated with the genetic resources of the country is found, as well as the

mandate to "establish the Regulatory Framework for Biosafety in Panama", which will be achieved thanks to the management of ANAM and the financial support of the GEF and UNEP.

IV. ACTIVITIES RELATED TO THE EXECUTION OF THE PROJECT

During the initial phase of the project, a set of activities was undertaken to formally establish the fund administrator, identify and create the National Coordination Committee, define its physical address of the office, draft the terms of reference and hire personnel for the national coordination of the project.

The main activities of the project will include the "Assessment of the situation regarding the national institutional capacities for the development of biotechnology and biosafety of genetically modified living organisms in Panama"; "Assessment of the commercialization of transgenic organisms in Panama" and the "Assessment of current legislation on the development of biotechnology and biosafety, especially regarding the use, handling, transfer and release of genetically modified living organisms in Panama and its relations with countries in the region".

The applied methodology was designed to identify, through specific paths, the types of activities carried out by the various institutions dealing with biotechnology in Panama. The paths considered were first of all research institutes and centers, universities, laboratories, importers of seeds, of veterinary products and of grains for the production of animal feed, situated in the city of Panama and in the interior of the country.

In developing the project it was considered fundamental to conduct inquiries and consult with the most experienced sectors, in order to be able to direct the assessments and confirm evaluations and conclusions at the end of the project.

Three inquiries on the "Perception of Modern Biotechnology in Panama" were organized, which were tried out with consumer groups, non-governmental organizations and competent authorities involved in the project. Likewise, working sessions were held with the members of the National Coordination Committee. In addition there were several meetings with technical consultants and decision makers addressing the following topics:

- Presentation of the background and objectives of the Project for a National Regulatory Framework for Biosafety in Panama
- Presentation of the history of the Cartagena Protocol on Biosafety
- Presentation of the current situation of biotechnology and biosafety at the regional and national level
- Presentation of the results of the assessments regarding the "Legal Framework", "Commercialization of Genetically Modified Living Organisms in Panama" and the "Present Situation of the National Institutional Capability for the Development of Biotechnology and Biosafety of Transgenic Organisms in Panama.
- Obtainment of commentaries and opinions on the results of the current

situation, the legal framework and the commercialization of genetically modified living organisms and biosafety in Panama.

- Drawing up of a plan for intersectorial training
- Approval of the draft for a "National Regulatory Framework for Biosafety in Panama".
- Presentation of the background and objectives of the Project for the Regulatory Framework on Biosafety in Panama.
- Presentation of the results of the technical work sessions on the Current Situation of Biotechnology and Biosafety at the regional and national level, The "Legal Framework" and the commercialization of genetically modified living organisms and biosafety in Panama.
- Approval of the draft for a "Regulatory Framework for Biosafety and Biotechnology in Panama".

It was also agreed upon to hold a series of meetings to allow the members of the National Project Coordination Committee to evaluate the progress made and to present its corresponding recommendations. One of the topics remaining pending is the organization of a short course on "Biosafety in the Use of Transgenic Organisms and the Cartagena Protocol on Biosafety", which has become one of the most urgent priorities necessary for the implementation of the regulatory framework; it is hoped that it may be held in the coming months.

V. REGULATORY REGIME: LEGAL FRAMEWORK CURRENTLY IN FORCE

The result of the "Assessment of the valid legislation for the development of biotechnology and biosafety, especially regarding the use, handling, transfer and release of genetically modified living organisms in Panama and its relations with countries in the region" is one of the major outcomes of the project, as it not only presents an overview of the reality in the nation, but also offers a comparison of regional standards, looking for common elements and experiences in the field of, use, release, transboundary and internal movement of genetically modified living organisms. This exercise has shown us the achievements which have served to compare the proposals finally adopted in Panama.

Within the national legislation, the following laws form the basis of current jurisdiction and support the proposed national framework:

- **Law No. 9 of 8th June 1992**

approves the International Convention on Phytosanitary Protection, revised on the 28th of November, 1979, by the United Nations Food and Agricultural Organization. G.O. 22,057 of June 16th, 1992.

This convention intends to ensure common and efficient action for the prevention of plant pests and introduction of vegetable products as well as to promote adequate control measures. Under this concept it is understood that the decrees of

the convention extend to any other organism capable of harboring or dispersing plant pests, especially regarding international transport. Relevant for this subject are the International Norms for Phytosanitary Measures (NIMF), issued by the Secretariat of the International Convention on Phytosanitary Protection, among which we have NIMF No. 11 (2004), titled: Risk Analysis of Diseases, for pests subject to quarantine, including analysis of environmental risks and genetically modified living organisms; applied by the National Management for Plant Health of the MIDA.

▪ **Law No. 2 of 2nd January 1995**

approves the Convention on Biological Diversity, agreed upon in Rio de Janeiro on June 5th, 1992. G.O. 22,704 of January 17th, 1995. Article 19, Management of Biotechnology and Distribution of its Benefits, establishes that:

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

▪ **Law No. 47 of 9th July 1996**

enacts measures for phytosanitary protection, among other dispositions. G.O. 23,078 of July 12th, 1996. This law regulates "... any actions relative to the protection of plants of the national agricultural heritage, with the fundamental objective to prevent and comprehensively control phytosanitary problems and to obtain phytosanitary quality of plants and their produce in the course of their production, their classification, packaging, storing and transport, as well as to avoid the introduction, taking root and spreading of plant pests and produce in the territory of the Republic of Panama.

Among the objectives listed in article 2 of this law, under number 9 the following is expressly mentioned: "Facilitate the development and use of biotechnology as a means to solve problems which are specific to the sector, as well as surveillance, registration and control of transgenic material".

▪ **Law No. 72 of 26th December 2001**

approves the Cartagena Protocol on Biosafety of the Convention on Biological Diversity established in Montreal on the 29th of January, 2000. G:O: 24,460 of December 28th, 2001. It deals specifically with transboundary movement, and its objective is to contribute to guarantee an adequate level of protection in the area of safe transfer, handling and use of modified living organisms of biotechnological origin, which may have adverse effects on the conservation and sustainable utilization of biological diversity, taking also into account the risks for human health.

▪ **Law No. 8 of 24th January 2002**

establishes the national regulations for the development of organic agricultural and livestock activities. G:O: 24,482 of 30th January, 2002.

This law intends to contribute to a comprehensive development of agriculture, implementing and initiating programs for scientific research, technological development and innovation in the field of new techniques in sustainable agriculture, as well as organic agricultural practice, promoting active transfer of the knowledge and technologies to the productive sector. It also creates the National Committee for Organic Agriculture as a consulting body to the Executive Body and thereby indicates that the Republic of Panama complies with the the Codex Alimentarius of the United Nations Food and Agricultural Organization (FAO).

▪ **Law No. 48 of 8th August 2002**

creates the National Committee on Biosafety for Genetically Modified Organisms and lays down other provisions. G.O. 24,617 of 14th August, 2002. The committee created with this law has the object of establishing and coordinating the policies of the state of Panama regarding rules of handling genetically modified organisms, their by-products and products that contain them, in order to prevent risks and to minimize impacts on the environment, biodiversity, human health and agricultural production which may arise as a result of activities carried out with these organisms.

▪ **Resolution No. 011 of 23rd January 2002 (MINSA)**

from the regulations issued by the National Committee for Biosafety. G.O. 24,493 of February 18th, 2002. The regulation defines biosafety as the set of norms concerning the preventive behavior of persons in the different fields facing the risks generated by their activity.

▪ **Resolution No. ALP-093-ADM of 24th October 1997 (MIDA)**

resolves to establish the procedures and phytosanitary requisites for any natural person or legal entity desiring to import plants, vegetable products and merchandise in transit. G.O. 23,413 of November 6th, 1997.

In general terms, a phytosanitary license from the Executive Department for Agricultural Quarantine and a phytosanitary risk analysis by the National Department of Plant Health and its respective license are required, as well as verifications by the Executive Department for Quarantine, which will either issue or refuse the phytosanitary import license.

Notwithstanding the number of legal instruments which the state of Panama has adhered to, no legislation supporting common and efficient action for prevention and coordination of appropriate measures to control cross-border movement of genetically modified living organisms is expected. It has been left to the National Department for Plant Health of the Ministry for Agricultural Development to issue due authorization to a person desiring to import, research, experiment with, move, release into the environment, reproduce or commercialize transgenic plants or their products, biological control agents or other types of organisms for agricultural use, whether created in or outside the country; subject to regulation issued by the responsible authorities, who so far do not, however, have the necessary instruments for this purpose at their disposal.

The new Panamanian Food Safety Authority issues permits for importing alimentary products, which could, in the future, also include alimentary products for human or animal consumption containing genetically modified living organisms.

Although no requests for authorization have been received so far, and it is not officially known whether permits are presently being issued for importing or commercializing transgenic seeds in this country, it cannot be excluded that this is happening, due to the lack of knowledge and controls. The same is true for genetically modified veterinary products.

In general it can be assumed that there is great ignorance about regulations on these matters, as well as considerable indifference towards the topic of biotechnology, except for the few who conduct research with meager resources and who are mainly isolated in research institutes or centers and in universities.

VI: SYSTEMS FOR THE FOLLOW-UP, CONTROL AND MONITORING OF GENETICALLY MODIFIED LIVING ORGANISMS

The decrees introduced in the legal administration regarding the flow of genetically modified living organisms imported or subject to be imported, according to Law no. 48 of the 9th of August, 2002, "which creates the National Committee for Biosafety and lays down other provisions", are presented in figure 1. In this law, responsibility is given to the Ministry of Agricultural Development (MIDA), through the Panamanian Institute for Agricultural Research (IDIAP), to conduct the risk assessment on matters of biosafety for genetically modified living organisms in the

agricultural sector. Concerning genetically modified living organisms liable to affect human health, it is the responsibility of the Ministry of Health, through the Gorgas Memorial Institute for Health Studies, to conduct risk assessments on matters of biosafety. Concerning the release into the environment of genetically modified living organisms, responsibilities lie with ANAM and MIDA. Once the assessment is concluded, depending on the type of genetically modified living organisms, the respective ministry presents a report to the Sectorial Committee for Biosafety, be it the one for Agriculture and Environment or for Health, which will then authorize or refuse the request. In turn, these Committees for Biosafety send the respective minutes of the deliberative meetings and the technical report to the Technical Secretariat of the National Committee for Biosafety.

The Committee for Biosafety may invite representatives of state agencies or organizations, national or international experts and representatives of the community to participate in the agreements and decisions of matters related to their field of competence, with a right to be heard but no right to vote.

Among the principal functions of the National Committee for Biosafety are:

1. Establish and present national policies in matters of biosafety regarding modified living organisms, their inclusion in the sectorial programs to the Executive Body and to inform it on the progress of the activities it is in charge of.
2. Propose the updating and improvement of the legal framework for matters in its competence
3. Recommend institutional adjustments necessary for the competent entities to acquire sufficient institutional capability in the subject and adopt the standards on the introduction, use, research, handling, release into the environment, commercialization and industrial application in this country, of modified living organisms as well as of the raw materials and other products derived from them, in order to prevent, reduce, control or mitigate possible damage that might arise for human health, agricultural production or the environment.
4. Serve as the coordinating agency for activities related to the biosafety of modified living organisms and supported by corporations, legal entities and natural persons, public or private
5. Ensure, in accordance with valid legal regulations, that the criteria for the procedures for granting of authorization, licenses and permits to engage in the abovementioned activities are homogeneous and in keeping with administrative simplification.
6. Ensure scientific and technical cooperation on the national and international level in order to comply with the rules laid down in the CPB as well as supranational standards which are adopted on these matters
7. Recommend, whenever it is deemed necessary to reach a decision, assigning additional studies and procurement of necessary information in order to perform the function of monitoring, supervision, tracking and evaluation of the activities authorized by the Sectorial Committees for Biosafety of the Environment, Agriculture and Health.
8. Ensure permanent updating of a national and international register of modified living organisms as a precautionary principle.

9. Ensure the establishment of a data bank on the presence and distribution of wild species and their relation with modified living organisms which might be released and the mechanisms for monitoring and evaluation of the impact on the environment, human and animal health, and derivatives of the release, production and consumption of said organisms, their products and sub-products.
10. Ensure the equality and sustainability of the exploitation of the resources and capacities of the different institutions of the public and private sectors active in matters which are the object of the National Committee for Biosafety of GModified Living Organisms.
11. Encourage the application of efficient control and monitoring policies in order to fulfill the legal and regulatory stipulations.
12. Recommend, as a precautionary principle, the criteria which will have to be included in the corresponding regulation, in order to make the benefits and possible risks of the use of modified living organisms authorized for commercial application publicly known, according to the available technical and scientific information.
13. Promote research projects of national interest regarding modified living organisms.
14. Propose, in agreement with valid legal regulations, technological transfer to those programs which, in one form or the other, are related to the use of modified living organisms.
15. Attend meetings regarding matters in the realm of the National Committee and solicit concepts in matters of genetically modified living organisms.
16. Ensure, together with the Ministry of Foreign Affairs, that the members of the Panamanian delegations and representations to the events and international organizations dealing with these matters analyze jointly the national position of negotiation which they intend to take at said events, without prejudice to the appointments and recommendations which are of the competence of the corresponding sections, in accordance with applicable provisions.
17. Ensure the systematization of national and international information relevant to the functions of the National Committee, as well as the establishment of an informational service, advice and consumer service and support with regard to modified living organisms.
18. Publish the regulations and the manual of operation of the National Committee.
19. Recommend the application of appropriate sanctions to the relevant authorities.
20. Obtain information on international legal proceedings and incidents in matters of modified living organisms, in which the Republic of Panama is involved.

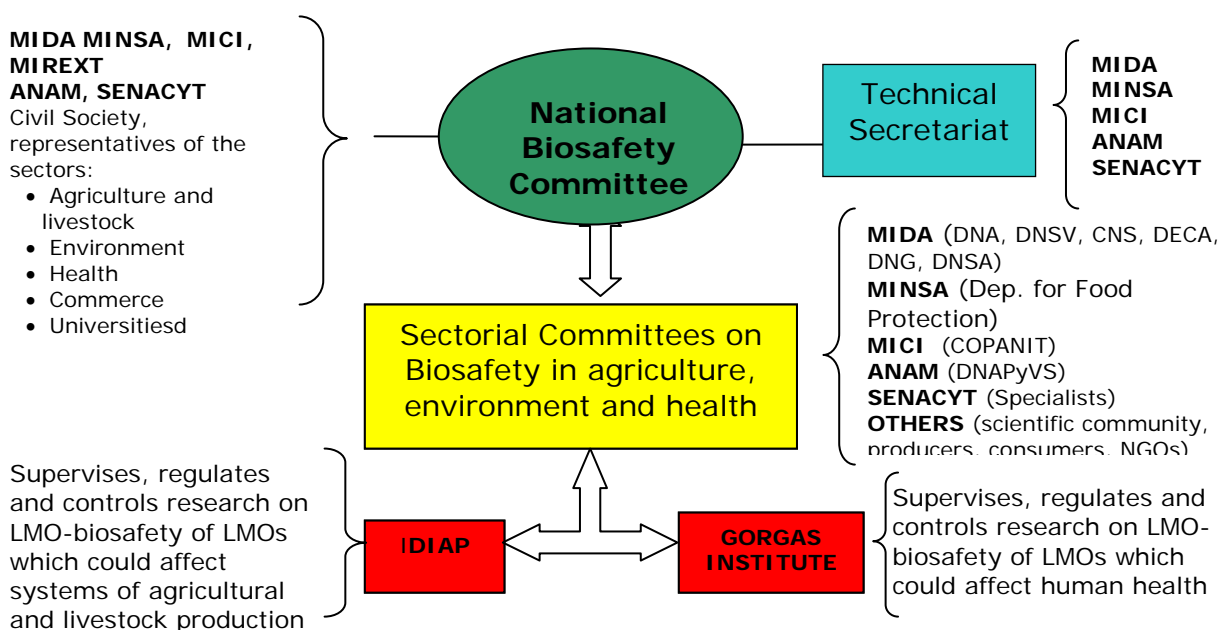
There are no other effective mechanisms, besides the functions of the National Committees for Biosafety, to perform tracing, monitoring and control activities at the different stages in the use of genetically modified living organisms in this country.

VII. ADMINISTRATIVE REGIME CURRENTLY IN PLACE

Law N° 48 of the 8th of August, 2002, "which creates the National Committee for Biosafety and lays down other provisions", rules that the National Committee should nominate a Technical Secretariat which will be coordinated by the Minister for Agricultural Development, and also that the Sectorial Committees for Agriculture, Environment and Health will be installed to regulate everything regarding the procedures of biosafety, risk analysis, monitoring and follow-up on any research, use or limited handling, laboratory experiments, release into the environment, greenhouses, crop protection (mesh netting) and experimental lots of genetically modified living organisms in their respective areas of responsibility. There are, nevertheless, serious limitations in the relevant administrative system, such as:

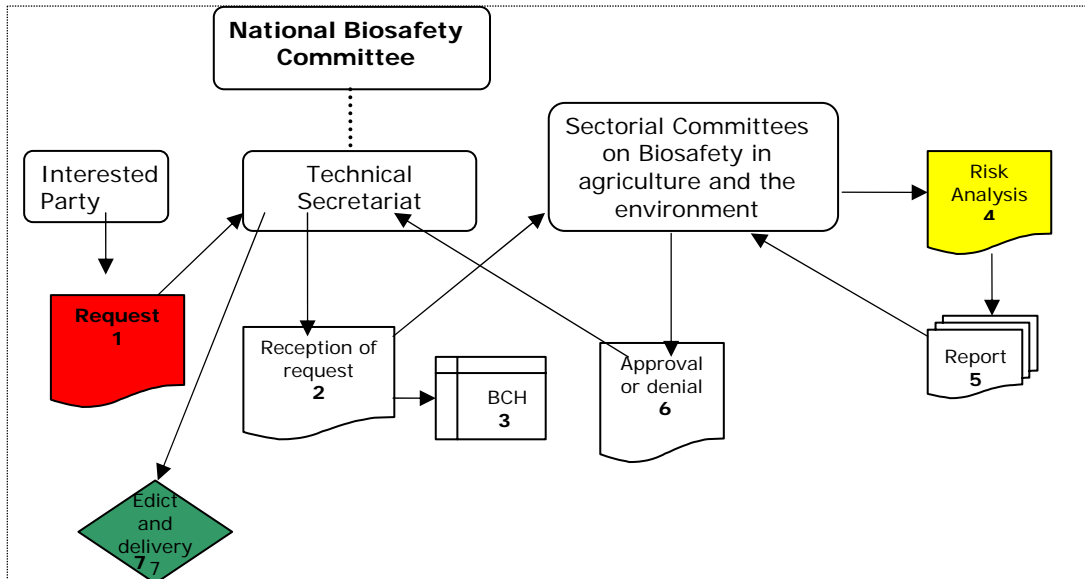
1. There are no procedures to administrate risk evaluation and risk management for modified living organisms destined to storage, intentional release or use as food or feed or for processing.
2. There are no standards for evaluations in the case of greenhouses or fields.
3. No criteria have been laid down for the definition of distance standards for isolation in the case of intentional release into the environment.
4. There is only limited capacity to conduct evaluations of environmental biosafety regarding the harmlessness of food from modified living organisms.
5. There is neither a system of information on biosafety nor of training of human capacities to increase the competence of staff involved with conducting risk analyses.
6. There is no tracing system available that would include protocols for the extraction of samples or for detection.

Chart 1. Current administrative scheme of the flow of genetically modified living organisms imported or intended for import, according to law N° 48 of 8th August 2002.



Technical outlines which govern the current procedure for importing genetically modified living organisms for confined use (research) and intentional introduction into the environment (seeds) are presented in chart 2.

Chart 2. Current procedure for importing genetically modified living organisms for confined use and intentional introduction into the environment, according to Law N° 48 of 8th August 2002.

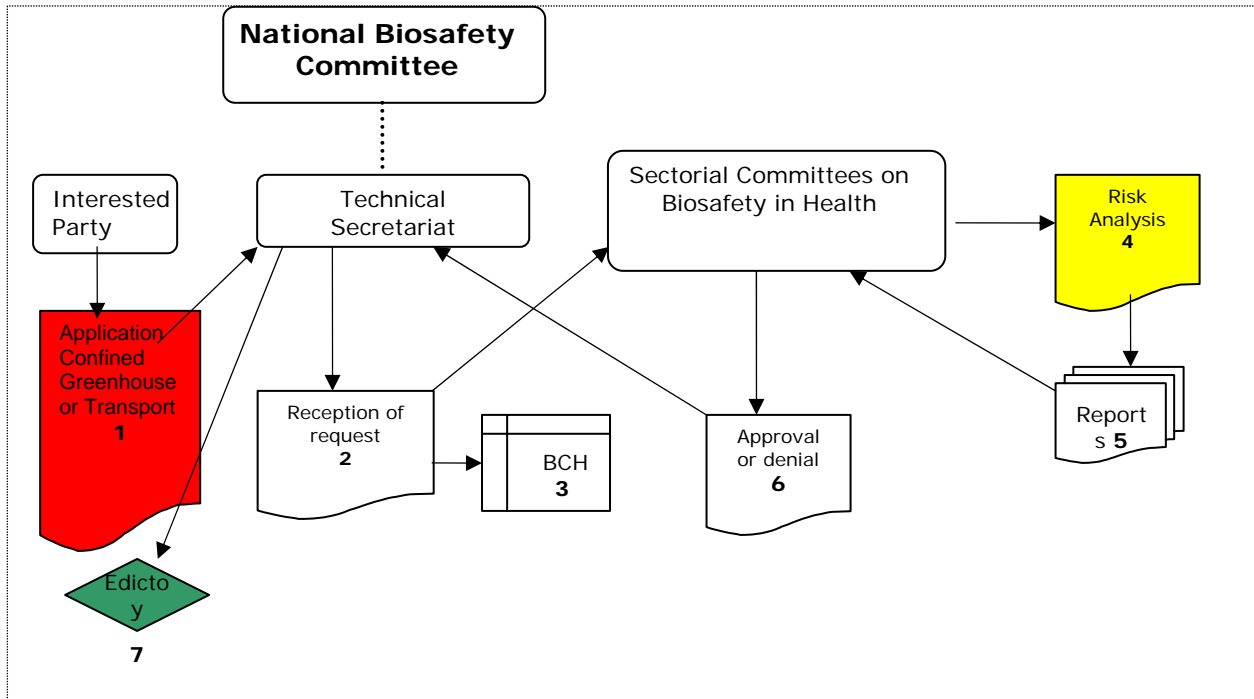


Approved procedures in force until the adoption of proposed amendments establish the following course of action:

1. Presentation of request by the interested party
2. Reception of the request by the Technical Secretariat
3. Registration at the Biosafety Clearing House (BCH) to be assigned. Forwarding to the Sectorial Committee for Biosafety in Agriculture and Environment.
4. Risk analysis of the request by the Sectorial Committee for Biosafety in Agriculture and Environment. (There is, at present, no technical procedure available to accomplish this.)
5. Drawing up and forwarding of a report to the Sectorial Committee for Biosafety in Agriculture and Environment.
6. The Sectorial Committee for Biosafety in Agriculture and Environment will approve or refuse. Forwarding of a report to the Technical Secretariat.
7. The Technical Secretariat edits, prints and sends a report to the applicant

The flow chart for a request for authorization of genetically modified living organisms intended directly as food for humans or animals or for processing. Is presented in Chart 3.

Chart 3. Current course of processing a request for genetically modified living organisms intended directly as food for humans or animals or for processing, according to law N°48 of 8th August 2002



The Procedure is as follows:

1. Presentation of the request by the interested party
2. Reception of the request by the Technical Secretariat
3. Registration at the Biosafety Clearing House (BCH). Forwarding to the Sectorial Health Committee.
4. Risk analysis of the request by the Sectorial Committee for Biosafety in Health. (There is, at present, no technical procedure available to accomplish this.)
5. Drawing up and forwarding of a report to the Sectorial Committee for Biosafety in Health.
6. The Sectorial Committee for Biosafety in Health will approve or refuse. Forwarding of a report to the Technical Secretariat.
7. The Technical Secretariat edits, prints and sends a report to the applicant

VIII. COMMERCIALIZATION OF GENETICALLY MODIFIED LIVING ORGANISMS

The location and concentration of commercial activity in the Panamanian isthmus has resulted in an increase of international trade movements, without the possibility to know its contents for sure. The awareness of this situation influenced the analysis of the three groups of genetically modified living organisms which could reach this country; for this reason, their commercialization can be regarded as being in agreement with the classification of the CP, namely:

1. Genetically modified living organisms intended for confined use (research): Up to this moment, no company importing or trading in seeds has officially registered with or applied for permission from The National Seeds Committee to enter transgenic seeds for the purpose of conducting tests under confined conditions, locally, although some companies have manifested their interest to consider this possibility. It can be assured that no permit has officially been granted to import transgenic plant seeds or animals into this country for tests under confined conditions. As to the companies importing or trading in veterinary products, they declared that none of the products they are usually selling, i.e. antibiotics, pesticides and vitamins, have been genetically modified. Just as the seed importing and trading companies, they also showed interest for regulation on this matter before considering this possibility. Officially, transgenic veterinary products are neither imported nor commercialized in this country.

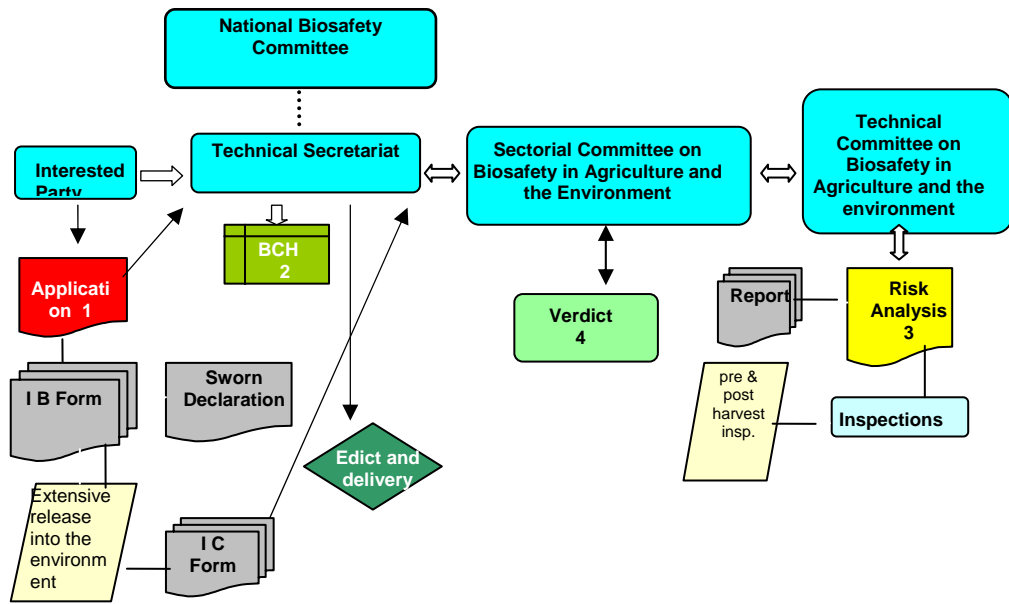
2. Genetically modified living organisms intended directly for food to humans or animals or for processing (grains): Grain importing companies using soybeans and corn as raw material for the production of animal feed import these from the United States, the principal and traditional export market. In 2005, figures were substantial for imports from Argentina. 148,760 tons of corn in grains were imported from the United States in 2006, as well as 120,000 tons of soybeans in grains and 126.5 tons of flour. Corn in grains entering this country has to meet the import requirements, namely:

- a) Approval of the import quota by the Consulting Committee for Corn and Sorghum
- b) Compliance with the phytosanitary requirements laid down by the National Office for Vegetable Health of the MIDA
- c) Phytosanitary Licence issued by the Executive Office for Agricultural Quarantine of the MIDA.
- d) Payment for clearance of the shipment to the General Customs Office.

The purchase of corn is done through agreements between grain importers and the Ministry for Agricultural Development. The quotas in the case of shortage are derived from the obligation of the interested parties to buy at first the national production at prices agreed upon between them and the National Association of Corn and Sorghum Producers, with the Ministry for Agricultural Development as mediator and guarantor of the agreements reached. Currently, no analyses are made of soybeans or flour to determine whether they are derivatives of transgenic plants.

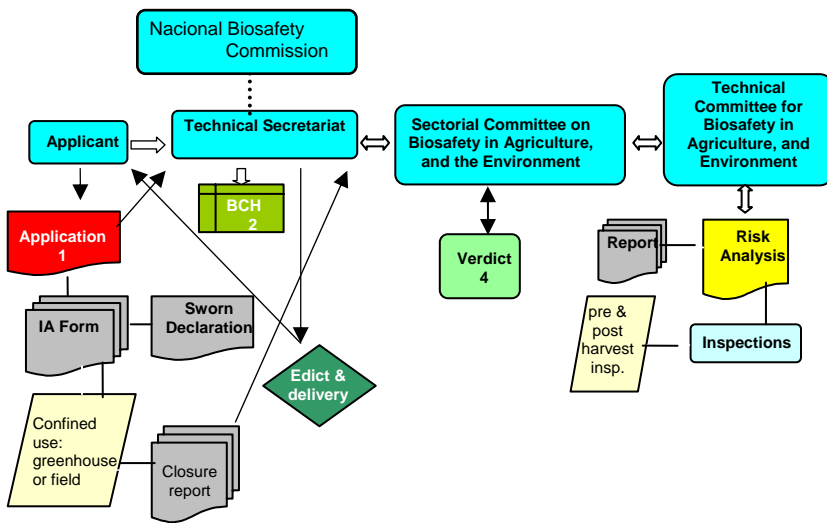
3. Genetically modified living organisms intended for intentional introduction into the environment (seeds): Just as for genetically modified living organisms for confined use (research), seeds meant for intentional introduction into the environment require an application by seed importers and distributors. Chart 4 shows the proposed course of processing a request for genetically modified living organisms for intentional introduction into the environment.

Chart 4. Processing a request for genetically modified living organisms for intentional introduction into the environment:

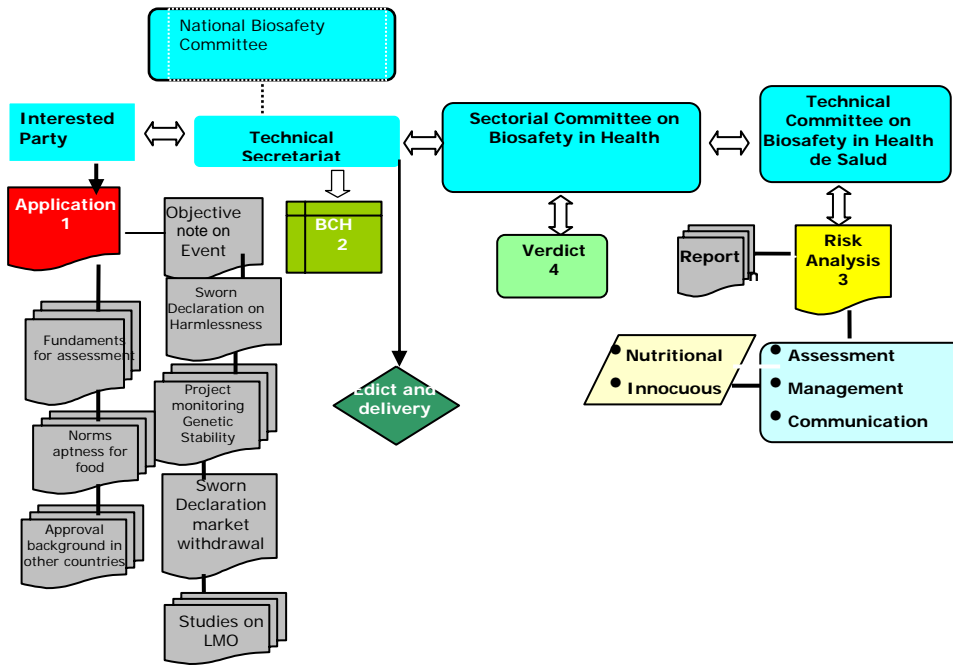


The flow chart for genetically modified living organisms intended for confined use is presented in Chart 5.

Chart 5: Flow chart for genetically modified living organisms intended for confined use.



The flow chart for genetically modified living organisms intended for extensive release is presented in chart 6



Transit and transport of grains and seeds through the Panama Canal

In 2005, the number of ships passing through the Panama Canal transporting grains between the Pacific and Atlantic Ocean amounted to 2,476, with a total of 52.054 million **PC/SUAB** tons net and a payment of 151.961 million US\$ for canal fees. Among the different types of ships passing through the Panama Canal, transport of grains represents 7% of passages and 17% of cargoes, consisting mainly of barley, corn, oats, rice, sorghum, soybeans and wheat. Seeds of various other crops and seeds of oleaginous plants are also being transported, without determination of whether they are transgenic or not. Cargo documents do not specify seeds or grains which could be of transgenic origin. This information is not requested by the Dry Bulk Section (*Sección de Graneles Seco*), a Unit of the Panama Canal Authority (ACP), which is responsible to control this kind of cargo.

Ships requesting permission of passage are under obligation to declare when they transport dangerous cargo. Consequently, as grains and seeds are not considered as dangerous cargo, they are not required to supply information on this subject.

Take, for example, cargo of corn or soybeans from the United States and Argentina arriving at the port of Cristobal on the Atlantic coast: on certain occasions the "graneleros" (i.e. ships transporting grains), passing through the canal from the Caribbean to the Pacific, may unload the cargo in the port of Balboa, where officials of the National Office for Plant Health take samples to check for the presence of insects.

The cargo is released as soon as the analysis by the laboratory confirms that it contains no insects or diseases. No samples are taken from this cargo to check for the presence of genetically modified living organisms.

The ship is unloaded by cranes which shovel the grains out of the hold and via funnels onto trucks. It is hoped to modernize this is slow and manual process in the coming years with the construction of this country's first grain terminal on quay 16 in the port of Cristobal, Colon. This terminal will have a capacity for unloading 10,000 tons per day. It will also have three silos for storage: two vertical silos with a capacity of 7,500 tons each for corn and a horizontal one with a capacity for 6,500 tons for soybeans.

To transport grain in bulk, import companies use trucks which transfer the raw material to their processing plants in the cities of Panama, Capira or Santiago de Veraguas. During that process, the cargo is neither controlled, nor are any samples taken to check for the presence of genetically modified living organisms.

Labeling and identification of transgenic products

Law n° 29 of the 1st of February, 1996, stipulates in article 31, section 1, that a supplier must give clear and true information to the consumer in the case of food products which require warnings or precautions, although it does not specify or make reference to transgenic products.

With the creation of the Panamanian Authority for Food Safety (AUPSA), the state extends its responsibility by charging this institution with establishing norms regarding introduction of food products, whose eligibility and requirements for import will be established by risk analysis. The powers that previously lay with the Ministries for Agricultural Development and Health have been transferred to AUPSA, including, of course, the requirements for the introduction of products and derivatives of genetically modified living organisms.

IX. APPLICATION FOR COMMERCIAL RELEASE OF GENETICALLY MODIFIED LIVING ORGANISMS INTO THE ENVIRONMENT

According to current rules, authorization for commercial release of genetically modified living organisms into the environment for agricultural purposes is granted by the chairperson of the National Biosafety Committee, based on two (2) independent assessments delivered by consulting organizations attached to the Technical Secretariat of the CNB:

- a) A proof that extensive release of genetically modified living organisms into the environment would generate an impact which differs significantly from the one produced by an equivalent conventional organism. This assessment is delivered by the CNB through the Sectorial Committee for Agricultural and Environmental Biosafety.
- b) Proof of fitness for human or animal consumption or for processing of foodstuff containing genetically modified living organisms. This assessment is delivered by the CNB through the Sectorial Committee for Health Biosafety.

The Sectorial Committee for Biosafety in Agriculture and Environment is in charge of evaluating all requests for releases of genetically modified living organisms into the environment, and to deliver them to the Technical Secretariat of the CNBB,

assessing whether or not it is convenient to authorize such releases in two phases:

1. First phase of assessment: Assessment of the experimental releases, the purpose of which is to determine that the probability of effects on the environment is not significant.
2. Second phase of assessment: Assessment of the extensive releases, the purpose of which is to determine that said releases of genetically modified living organisms do not generate an impact on the environment differing significantly from that of an equivalent not genetically modified organism.

With the proposed modifications of law n° 48 of 2002 and its regulations, the decrees and procedures regarding authorization to release genetically modified living organisms commercially and into the environment for agricultural use are becoming more technical; it is for the appropriate authorities to grant the authorizations, based on the advice and assessment issued by the National Technical Committee for Biosafety and the Sectorial Technical Committees.

X. PLAN OF ACTION FOR THE CREATION OF BIOSAFETY CAPACITIES

Control and surveillance of the transit and transboundary movement being an difficult task, the capability for adequate response depends on the effectiveness of the coordination between government institutions, training of appropriate staff, according to the priorities established by each institution and the allocated resources. The plans and programs for strengthening capacities to respond to various risks potentially resulting from these activities include the reinforcement of legal structures and regulations as well as the procedures for consulting the technical-scientific community and the public in general. The biosafety measures which will be adopted and are acceptable to Panama will be the ones decided upon by those who are capable to responsibly project the objectives of the regulatory framework with the pressures from and interests of the industry which processes genetically modified living organisms and their derivatives. It will depend largely on the guidelines keeping the equilibrium between the interests of the scientific community, the trade in the new biotechnologies and the principle of precaution which has to be paramount at all times.

As Panama is a receiving country of biotechnology, political and commercial obligations can take precedence over scientific and technical considerations. The population may find itself face to face with side effects with negative consequences for their health and environment.

Among the main objectives of a program for institutional training and strengthening are:

- To update the administrative and technical knowledge, methods and procedures regarding the use, transport and cross-border movement of genetically modified living organisms among the actors in the process of implementing the national regulatory framework.

- To raise awareness among the representatives of consumers, producers, governmental and non-governmental institutions in order to achieve adequate knowledge of the subject, which will make the implementation of the national regulatory framework easier.
- To identify means of education to be implemented in the short, medium and long terms to facilitate understanding and broaden the discussion of the subject.
- To inform the representatives of consumers, producers, governmental and non-governmental institutions on current procedures and criteria for risk analysis and on biosafety measures taken by each participating institution of the CNB.
- To promote a change of attitude among the actors of society to obtain an suitable social environment for an adequate implementation of the law.
- To identify short and medium term actions to make the implementation of the law regulating the management of genetically modified living organisms easier.

Based on the requirements for the creation of biosafety capacities identified during inquiries and technical sessions and with decision makers, various themes have been suggested, which were divided into six groups: Development of a set of rules for biotechnological safety; creation and long term maintenance of the rules; risk assessment; risk management and risk communication, as shown in table 1:

Table 1. Themes for the creation of biotechnological capability by components

Component	Themes
Assessment of requirements and planning of the framework for biotechnological safety	<ol style="list-style-type: none"> 1. Inventory of existing and anticipated programs and procedures related to biotechnology 2. Collection of data on present and future imports and exports 3. Compilation and analysis of existing legal and administrative rules on biosafety 4. Biosafety rules involving other international commitments
Development of a set of rules for biotechnological safety	<ol style="list-style-type: none"> 1. Development/reinforcement of legal and regulatory structures 2. Procedures for safe handling, use and transport of genetically modified living organisms 3. Development/reinforcement of administrative procedures for handling risk assessment and risk management 4. Development of capability for national risk assessment 5. Handling of notification and examination

	<p>procedures and decisions</p> <p>6. Notification, emergency planning and response capacities</p>
Creation and long-term maintenance of the regimes	<ol style="list-style-type: none"> 1. Supervising, monitoring and notifying on the efficiency of the risk management program, including legal, regulatory and administrative mechanisms 2. Supervision of the environmental impacts in the longest possible term, if any (on the current bases of reference) 3. Installation of systems of notification on the environment
Risk assessment	<ol style="list-style-type: none"> 1. Drafting and application of procedures for risk assessment 2. Multidisciplinary risk analyses 3. Improvement of technological and institutional capacities for risk assessment 4. Risk analysis of conservation and sustainable use of biological diversity 5. Analysis of the life cycle of genetically modified living organisms 6. Analysis of risk genetically modified living organisms for human health and the effects on biological diversity 7. Analysis of the effects of the introduction of genetically modified living organisms on the ecosystem 8. Analysis of questions of food safety arising from risks to biological diversity 9. Usefulness and role of biological diversity for local and indigenous communities
Risk management	<ol style="list-style-type: none"> 1. Assessment of genetic modifications 2. Assessment of interactions between genetically modified living organisms and the receiving environment 3. Identification and quantification of the risks related to genetically modified living organisms, including safe application of the preventive approach 4. Assessment of the relative efficiency of the management options for import, handling and usage of genetically modified living organisms, if applicable. 5. Assessment of commercial consequences of genetically modified living organisms according to the administrative options, if any 6. Impartial examination of the proposed management

	regime before making decisions on genetically modified living organisms
Risk communication	<ol style="list-style-type: none"> 1. Collecting and exchanging of scientific information on genetically modified living organisms 2. Negotiations with the private sector, offering them opportunities for participation 3. Holding consultations with the community and ONGs to carry out risk assessments and implement management regimes for genetically modified living organisms. 4. Holding consultations with the community and ONGs before making decisions on genetically modified living organisms 5. Creating awareness with scientists and government officials for modern biotechnology and biosafety in the use of genetically modified living organisms.

Source: Assessment of the present institutional, national and international capacities for the development of biotechnology and biosafety for the use, handling, transport and release of transgenic organisms in Panama. Sanchez, M., ANAM, 2007.

More details on institutional training and strengthening are to be found in the document "Program for Institutional Training and Efficiency", which forms part of the results of the consultations held to prepare the present report.

XI. PROPOSAL OF A NATIONAL REGULATORY FRAMEWORK FOR THE BIOSAFETY OF GENETICALLY MODIFIED LIVING ORGANISMS

The proposal under consideration was drafted taking into account the experiences of the last five years and the necessity to adjust them to the changes and modalities of the new structures of the national government. In it, the national interest for the conservation of the biological diversity is coupled with the protection of human health and the environment. It concentrated on an exhaustive analysis of the local offer and its shortcomings, with the participation of all parties involved in this subject, seeking to assess the possible risks, obligations and benefits for Panamanians. The predominant multi-sector approach is the result of a comparative analysis between the missions of each of these entities and the responsibilities they have according to the regulatory instrument guiding them. The most important aspects make reference to the definition of the involved organisms, giving preference to the term "genetically modified living organisms". It was equally agreed to assign the National Biosafety Committee the task to establish the policy of the Panamanian state, the rules, regulations and procedures regarding biosafety in the use of genetically modified living organisms, products and their derivatives and products containing them, resulting from modern biotechnology, with the aim to avoid risks and minimize impacts on the environment, biological diversity, human health and agriculture at a national level.

A broader approach is introduced regarding the purpose of this law, which is the establishment and coordination of the policies of the state for activities carried out through modern biotechnology, regarding biosafety, ordering, handling of genetically modified living organisms, products and their derivatives and products that contain them, risk prevention and the minimization of impact on the environment, biodiversity, human health and agricultural production..

On the other hand, more competences are given to sectorial authorities regarding their participation in decisions about use, release and handling of genetically modified living organisms. The previous tasks regarding the handling and/or confined use, technical risk analyses and/or risk analyses, as well as permits to conduct research activities, confined use, tests with genetically modified organisms in hothouses, mesh tunnels, experimenting lots and technological development at research level, the conclusions and recommendations of which are presented by the responsible authorities to the CN for assessment and issuing a favorable or unfavorable opinion, are now delegated to the sectorial committees.

**FINAL DOCUMENT
FIRST PART**

**DRAFT BILL OF LAW N° _____
(X of xxxx of 2007)**

"That modifies and adds articles to Law 48 of 2002, that creates the National Biosafety Commission for Living Genetically Modified Organisms and dictates other dispositions"

→ FOR FULL LEGAL TEXT: Please see Spanish version of NBF (p36)

XII. EXECUTIVE DECREE THAT REGULATES MODIFICATIONS TO LAW 48 OF 2002. FINAL DRAFT.

Rationale:

Considering that Biotechnology, understood as the technological treatment of biological resources for industrial or agricultural purposes or for the promotion of human health, is a scientific, sociological, economic and political phenomenon with indisputable and growing repercussions in the life of all contemporary societies, state regulations on biosafety have become indispensable. The concept of biosafety developed in the present Executive Decree refers to genetically modified organisms, to biodiversity and to environmental sustainability as the basis for our national food security.

The present Executive Decree proposes regulations, procedures and requirements to prevent, minimize or eliminate risks related to the import, export, research, production, handling, management, education, technological development, consumption, release, movement, offer of services, dissemination and communication related to genetically modified organisms which could jeopardize the health of human beings, animals, plants and the environment.

During this process of drafting a national regulatory framework, international

treaties and agreements and the applicable national legislation on the matter have been taken into account, such as:

Law No. 2 of 1995, through which the Republic of Panama ratified the Convention on Biological Diversity;

Law No. 72 of December 26th 2001, through which the Republic of Panama ratified the Cartagena Protocol on Biosafety of the Convention on Biodiversity, held in Montreal on January 29th 2000;

Law No. 48 of 8th August 2002, which creates the National Committee on Biosafety and establishes other regulations as elements of the national legal framework for the implementation of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity.

This regulation is mainly aimed at preventing potentially adverse effects of living genetically modified organisms on human health, conservation and sustainable use of biodiversity and the environment.

Considering that modern biotechnology can contribute in manifold ways to the enhancement of human well-being, if it is developed under adequate safety measures and adopting ethical and bioethical parameters defined by the international scientific community and included in conventions and treaties on the matter; and that the management of the National Secretariat for Science, Technology and Innovation for the implementation of the National Science and Technology Plan promotes research and development through new technologies as part of the national competitiveness strategy, the present regulation on living genetically modified organisms is in conformity with Article 47 of Executive Decree 257 of October 17th 2006, which establishes requests for access to genetic and/or biological resources for research that may be linked, incorporated or applied to the sphere of transfer, genetic engineering, genetic use restriction technologies and living modified organisms, and in accordance with the precautionary approach, has the purpose of helping to guarantee an adequate level of protection in the transfer, manipulation and utilization of Living Genetically Modified Organisms, produced through biotechnological activities.

**SECOND PART
EXECUTIVE DECREE**

**REPUBLIC OF PANAMA
MINISTRY OF ECONOMY AND FINANCES
EXECUTIVE DECREE N° XX
(X of xxx of 2007)**

"That regulates the Law N° xx, of xxx of 2007, that modifies and adds articles to Law 48 of 2002, that creates the National Biosafety Commission for Living Genetically Modified Organisms and dictates other dispositions"

→ FOR FULL LEGAL TEXT: Please see Spanish version of NBF (p48)

XIII. PROGRAM FOR THE TRAINING OF HUMAN RESOURCES AND

INSTITUTIONAL STRENGTHENING IN MATTERS OF BIOSAFETY

The development of sectorial programs for institutional training and strengthening has been conceived as part of a strategy for national security, not only with respect to the risks inherent in the new technologies, but also according to the international commercial as well as environmental obligations. It appears fundamental to be able to consider, on the basis of sound criteria, the risks or advantages, dependence or independence, requiring a policy of biotechnological development which also comprises those other collateral aspects affecting the conservation of biological diversity and human health. For this reason, the program for training and qualification is an urgent task, which - if successfully accomplished - will ensure that the objectives of the Cartagena Protocol do not become mere declarations of intentions, disconnected from the national reality.

The methods for systematic inspections of the installations and areas of release as well as the assessment and monitoring of risks involved in the introduction of genetically modified products are some of the topics which have to figure permanently on the national agenda for these matters. At the same time, the requirements and guidelines defining the criteria for approvals have to be based on scientific strategies which comply with a national plan, not only for technical or commercial, but also long-term social and political development.

In view of the global importance of these scientific and commercial concepts, and the limitations and lack of infrastructure, technical and scientific experience and the financial resources for the institutions responsible for these tasks, a program is proposed which will, if possible:

- a) Reinforce the channels between institutions to develop the assessments of risks and effects on human health, biological diversity and agricultural and livestock production
- b) Reinforce institutional coordination to keep them up to date on biotechnological research carried out with national genetic resources in the national territory for their adaptation or release in the country
- c) Support the national universities, especially regarding development of programs for molecular biology and genetic engineering
- d) Assess the installed capacities and contribute to their perfection, in conformity with the requirements of the regulatory framework
- e) Enable all institutions to make use of the centre for information on biosafety of the Cartagena Protocol (CP) as a means of reference for all applications for introduction of products containing genetically modified living organisms approved in this country
- f) Establish a centre for public information in each of the institutions responsible for these guidelines, so that up to date information can be offered to users or parties interested in the subject

XIV. CONCLUSIONS

Technological innovation in genetic engineering has ceased to be an exercise of the few, having been able to energetically envelop the paths of economic and

commercial development without precedents from other discoveries. A great number of products have been introduced into the markets of developed and developing countries without any major limitations. Lack of expertise has partly left the field free for commercial exchange of products which may turn into a hazard for human health and for the environment.

Results of biotechnological innovation pouring out of universities and research institutes have flooded market segments from health to agriculture, maritime resources and the environment.

Medical and agricultural biotechnology, GM-plants, biological pest control, techniques for cultivation of tissues for agriculture, development of new vaccines and drawing up the genetic chart of the main crops represent some of the major achievements, but also a source of preoccupation for developing countries which, like Panama, do not have the ability to measure the impact the introduction of new technologies into the marine aquaculture may have on its vast biological diversity.

The fact that the innovations are strongly protected by the regulations on intellectual property has been felt by the economies of countries which, like Panama, are recipients and not generators of these technologies. Access to the technologies has to be facilitated, according to the Convention on Biological Diversity, at equitable conditions and on favorable terms, especially those protected by patents and intellectual property rights. Nevertheless, reality shows that these favorable terms continue to be very costly, if it is not known for sure which risks or benefits these technologies involve. Decisions to release genetically modified living organisms into the environment require sound criteria, methods and procedures which guarantee the safety of their application and/or use.

None of the committees and other bodies created concerning the subject under scrutiny has met the expectations, and in few or no instances have they fulfilled their duties. Therefore, it is strongly recommended to either avoid this mechanism of action or to set up an arrangement in which they are retained as consultants and given a specified deadline by which they have to present findings, otherwise their silence will have a positive effect, and the responsible authority, which has made the application, will decide according to its own judgment.

The National Biosafety Committee has started regulating the activities in matters of biosafety, seeking not only to contain the apparent risks, but also to safeguard investments in projects incorporating advances in these technologies. With this first step, implementation of the regulatory framework is started, and it is believed that the second step could give a strong impulse to the invigoration of the necessary processes to guarantee biosafety in Panama.

There is an urgent need to develop and implement the *National Regulatory Framework* for the biosafety of genetically modified living organisms for agricultural use, considering that many of the imports into this country, especially grains for human and animal consumption as well as processing, could actually contain genetically modified living organisms.

This situation means that the state has the obligation and responsibility to develop

the instruments and tools which are helpful to reach decisions, by applying case-by-case and step-by-step risk analysis regarding the "trinomial": a) transformation event, b) host organism and c) place of release, in order to avoid or minimize the risk through their commercialization.

The country possesses infrastructure, equipment and human capacity which has to be trained in risk analysis, taking samples and detection of genetically modified living organisms, in order to exercise the relevant controls for any food product imported from countries using these biotechnologies.

XV. RECOMMENDATIONS

Some recommendations, which are the result of various consultations at a national level and proposals of the institutions which are part of the National Biosafety Committee will be highlighted in order to emphasize those which have priority for the functioning of the national regulatory framework for biosafety, the following are mentioned:

1. Encourage adoption of the amendments and modifications of Law no. 48 and its prescriptions.
2. Design and implement the monitoring and control mechanisms for genetically modified living organisms.
3. Develop the rules for safe transit of genetically modified living organisms.
4. Identify sources of financing for the program for the training of human resources and institutional capacity-building.
5. Establish the National Biosafety Centre.
6. Formulate the protocols for risk assessment in each of the institutions forming part of the CNB.
7. Create an integrated system of monitoring, surveillance and rapid response to voluntary and accidental release of genetically modified living organisms.
8. Identify mechanisms and spaces to ensure public participation in decision making.
9. Adopt rules regarding the identification, packaging and labeling of products and derivatives of genetically modified living organisms.
10. Prepare a plan for the zoning for the use of genetically modified living organisms in the agricultural sector, together with a map of the areas suitable for these activities.
11. Train the staff of the National Customs Authority in inspection tasks and surveillance procedures regarding genetically modified living organisms.
12. Train the staff of the Public Ministry (Public Prosecution Office) and the Judicial Body in these regulations.
13. Draft a plan for capacity-building regarding this subject (general guidelines provided by this consultant in the present document).
14. Train the staff of each sector in conducting informational events and forums to increase dissemination and public participation around this subject.

15. Establish cooperation agreements with international entities and non-governmental organizations regarding risk verification.
16. Draft a National Plan for Biotechnology, taking advantage of the national consensus to produce a National Development Plan for the country.
17. Develop and implement the regulatory framework for:
 - Genetically modified living organisms that are plants intended for confined use (research), intentional introduction into the environment (seeds) → presented by this consultant in this document.
 - Genetically modified living organisms that are animals
 - Live modified micro-organisms (bioremediation)
 - Evaluation of food derived from genetically modified living organisms.
 - Conditions of isolation for intentional introduction into the environment.
18. Furthermore, as regards the obligations and responsibilities of Panama in compliance with the Cartagena Protocol, we propose that through an inter-institutional convention between the authorities of the Ministry for Agricultural Development (National Office of Plant Health) and the General Customs Authority, a system of controls be established to oblige the importers, in the case of any kind of transboundary movement, to declare his shipments or products, whichever they may be, free of genetically modified living organisms, and in case of their existence to refer the interested party to the National Office for Plant Health of the MIDA for appropriate controls and authorization.
19. It has to be mentioned that recommendations have been proposed at a regional level for every country, such as the suggestions made at regional workshops organized by OIRSA. In the year 2000, OIRSA organized a workshop on the Safety of Modern Biotechnology, during which two work groups of participants made the following recommendations:
 - Regarding transit and confined use of products meant for direct human consumption or animal feed or for processing:
 - For transit and confined use, norms on genetically modified living organisms should be harmonized on a regional level;
 - For products intended for direct human consumption, the option of introducing a moratorium for genetically modified live organisms, whose genetic resource has its centre of origin in the meso-American region, has to be assessed¹;
 - Regarding the application of the Prior Informed Agreement, notifications and decision-making:
 - Create a National Biosafety Committee, for which OIRSA should be the information exchange center;
 - Risk assessment and management:
 - The countries have to prioritize capability-building.
 - Regional harmonization of risk assessment and analysis for the

¹ Notes containing the recommendations of the workshop titled "Security of Modern Biotechnology", held in El Salvador in September, 2000).

release of genetically modified living organisms.

- Increase and expand the dissemination and training efforts at a regional level. ²
- On transboundary movements:
 - Urge OIRSA member countries to officially institute the responsible national authorities for the implementation of the Protocol.
 - As to packaging and identification, it is recommended that countries pass legislation to prevent the risk of handling, packaging and transport of genetically modified living organisms intended for confined use, indirect use and the intentional introduction into the environment.
 - Legislation in each country regarding sanctions for illegal movement of genetically modified living organisms should be harmonized.
- Regarding confidential information and raising public awareness:
 - The training of public servants has to be improved to guarantee confidentiality.
 - Information has to be classified
 - The information has to be clear and transparent for public participation.

XVI. BIBLIOGRAPHICAL REFERENCES

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² see note No. 31, p. 2.

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